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C	4610-0027
EXAMINER	
KUNZ, G	
ART UNIT	PAPER NUMBER

27

1803

DATE MAILED:

02/08/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7-25-94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 7-18, 20, 22, 27-38 AND 40-50 are pending in the application.
Of the above, claims 8-9, 11-18, 20, 22, 28-38, & 40-50 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 7, 10, & 27 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

07/652,978
PTOL-326 (Rev. 2/93)

EXAMINER'S ACTION

Applicant's election of the nucleotide species defined by claim 27 is acknowledged. Claims 7 and 10 are generic to this species and will be examined in so far as they pertain to this elected species. Claims 7 - 9, 11 - 18, 20, 22, 28 - 38, and 40 - 50 are withdrawn from consideration because they are directed to the non-elected inventions.

Any 35 USC statutes not cited in this Office action can be found cited in full in the Office action mailed January 25, 1992.

The specification states on page 6, lines 14 - 15 that "The novel 5'-methylene compounds that are described herein have useful antiviral or antitumour activities." However, the disclosure stops here ~~and~~ fails to specify which of the thousands of known viruses the compound is active against. Therefore, the specification is objected to for not enabling for the use of the elected nucleoside as either an antiviral agent or an antitumor agent Without such guidance the specification is simply an open invitation for the artisan to experiment to find out which virus the compound will inhibit. Such experimentation would create an undue burden upon the person of ordinary skill in the art wanting to practice the invention.

Claims 7, 10, and 27 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 7, 10, and 27 are rejected under 35 U.S.C. § 103 as being unpatentable over either Borthwick et al. (J. Med. Chem.

34: 907 0 914, 1991) or Chu et al. (Chem. Pharm. Bull. 37: 336 - 339, 1989) in view of Reist et al. (WO 84/04748).

The claims are directed to 9-(2-deoxy-2-fluoro-B-D-arabinofuranosyl) 5'-methylenephosphonate as defined by claim 27.

Borthwick et al. discloses unphosphorylated nucleoside of claim 27 on page 908, compound 17. In addition, Borthwick et al. teaches that this compound is an effective antiviral agent as shown in Table II, entry 17(AFG).

Chu et al. also discloses this same unphosphorylated nucleoside of claim 27 on page 338, compound VI. Chu et al. also teaches that this compound is an effective antiviral agent as shown in Table II on page 338.

Neither Borthwick et al. nor Chu et al. discloses the 5'-methylene phosphonate derivative of the nucleoside of claim 27.

However, Reist et al. does teach the 5'-phosphonate derivatives of known the antiviral nucleoside analogs, compounds 1 - 22. Such derivatives confer ^uto advantages upon the unphosphorylated compound: 1) reduced toxicity and 2) activity against cells resistant to the free nucleoside analog due to the fact that a thymidine kinase enzyme is not required for the compound to become a triphosphonate and then inhibit DNA polymerases (see pages 1 - 2 and claims 1 - 35)

Consequently, the claimed nucleoside 5'-phosphonate would have been obvious to the person of ordinary skill in the art at the time of the invention wanting to produce and use a

Serial No. 07/652,978
Art Unit 1803

-4-

derivative of a known antiviral nucleoside analog but with reduced toxicity and with the ability to inhibit viral growth in cells lacking thymidine kinase. Thus, the invention is prima facie obvious in the absence of clear and convincing evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Robinson, can be reached on (703) 308-2897. The fax phone number for this Group is (703) 305-3230.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DOUGLAS W. ROBINSON
SUPERVISORY PATENT EXAMINER
GROUP 1800

Gary L. Kunz, Ph.D.
February 3, 1995